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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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10/13/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/664,234

Applicant(s)

RUAN ET AL.

Examiner

DIANA JOHANNSEN

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-27,29,31-50 and 53 is/are pending in the application.
- 5a) Of the above claim(s) 1-24,42 and 43 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 25-27,29,31-41,44-50 and 53 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

FINAL ACTION

1. This action is responsive to the Office Action Response and Amendment filed July 25, 2011. Claims 25-26, 31-33, 37, 39-41, 44-45 and 49 have been amended. Claims 1-24 and 42-43 remain withdrawn and claims 25-27, 29, 31-41, 44-50 and 53 remain under consideration. Applicant's amendments and arguments have been thoroughly reviewed, and are persuasive in part, as indicated below. However, applicant's amendments have also necessitated new grounds of rejection, and all claims are rejected under 35 USC 112, first and second paragraphs, as indicated below. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/restrictions

3. Claims 1-24 and 42-43 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 9, 2005.

Claim Rejections - 35 USC § 112, second paragraph

4. With regard to the prior rejections of the claims under 35 USC 112, second paragraph, applicant has overcome each of those rejections by amending the claims to remove the indefinite language.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY

APPLICANT'S AMENDMENTS. It is particularly noted that the amendments to claims 39-41 such that those claims now depend from claim 25 have necessitated the inclusion of claims 39-41 in those rejections applicable to claim 25.

5. Claims 25-27, 29, 31-41, 44-50 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 and 39-41 are indefinite over the recitation of the limitation "the full-length coding sequence" in step (ii) of claim 25. There is insufficient antecedent basis for this limitation in the claim. It is noted that step (i) has been amended to remove the recitation "coding sequence of a" such that antecedent basis is lacking for this language in step (ii).

Claims 25 and 39-41 are indefinite over the references in claim 25 to "the 5' transcription start site" and "the 3' transcription endpoint" because it is unclear what is required by these claim limitations. Claim 25 as amended requires extracting 5' and 3' tags "including the "5' transcription start site" and "the 3' transcription endpoint," respectively. However, as these particular regions, and tags including them, are not discussed in the specification, it is unclear what is encompassed by these claim limitations. For example, would a single nucleotide corresponding the 5' end/3' end of a full length cDNA be considered as meeting the limitation "the 5' transcription start site"/"the 3' transcription endpoint," or does this language impart a requirement for a particular structure, or for, e.g., a tag of sufficient length that it meets the limitations

discussed in paragraph 87 of the specification? It is not clear what types of tags would be considered as including “the 5’ transcription start site” and “the 3’ transcription endpoint,” and which types would not. Accordingly, the manner in which this language further limits the claims and affects the metes and bounds thereof is not clear.

Claims 26-27, 29, 31-38, 44-50 and 53 are indefinite over the recitation of the limitation “the full-length coding sequence” in step (ii) of claim 26. There is insufficient antecedent basis for this limitation in the claim. It is noted that step (i) has been amended to remove the recitation “coding sequence of a” such that antecedent basis is lacking for this language in step (ii).

Claims 26-27, 29, 31-38, 44-50 and 53 are indefinite over the references in claim 26 to “the 5’ transcription start site” and “the 3’ transcription endpoint” because it is unclear what is required by these claim limitations. Claim 26 as amended requires providing a transcript having “a 5’ terminus including the “5’ transcription start site” and “a 3’ terminus including the 3’ transcription endpoint.” However, as these particular regions, and tags including them, are not discussed in the specification, it is unclear what is encompassed by these claim limitations. For example, would a single nucleotide corresponding the 5’ end/3’ end of a full length cDNA be considered as meeting the limitation “the 5’ transcription start site”/“the 3’ transcription endpoint,” or does this language impart a requirement for a particular structure, or for, e.g., a tag of sufficient length that it meets the length limitations discussed in, e.g., paragraph 87? It is not clear what types of tags would be considered as including “the 5’ transcription start site” and “the 3’ transcription endpoint,” and which types would not. Accordingly,

the manner in which this language further limits the claims and affects the metes and bounds thereof is not clear.

Claim 39 is indefinite over the recitation of the limitation "the genome sequence". There is insufficient antecedent basis for this limitation in the claim (as a "genome sequence" is not previously referenced). It is unclear what type of "genome sequence" is required by this language, and how it relates to the "genome mapping" of the claim.

Claim Rejections - 35 USC § 112, first paragraph

THE FOLLOWING REJECTION INCLUDES NEW GROUNDS NECESSITATED BY APPLICANT'S AMENDMENTS. It is particularly noted that the amendments to claims 39-41 such that those claims now depend from claim 25 have necessitated the inclusion of claims 39-41 in this rejection.

6. Claims 25-27, 29, 31-41, 44-50, and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

First, claims 25-27, 29, 31-41, 44-50 and 53 remain rejected for the reasons already of record because claims 25-26 (from which all other claims depend) continue to reference "the full-length coding sequence of the cDNA transcript," i.e., the language that forms the basis of the rejection. While it is noted that applicant has amended the claims to remove several instances of this language, claim 25 (in step (ii)) and claim

26(in step(ii)) continue to make reference to “the full-length coding sequence,” such that all of the claims continue to embrace new matter for reasons of record.

Additionally, the claims as amended recite “the 5’ transcription start site” and “the 3’ transcription endpoint” of a cDNA transcript. These terms are not employed in the originally filed specification (and are also unclear for the reasons noted above). As previously noted on the record, the originally filed specification does disclose the preparation of ditags from full-length cDNAs. Further, the specification at paragraph 147 discloses that such ditags include “paired 5’ and 3’ signature sequences (tags) of a transcript in a ditag” that delineate “the starting and ending points of transcripts,” such that the specification provides basis for a ditag including a pair of sequences corresponding to the starting and ending points of a full-length cDNA transcript. However, the instant claims (while unclear) appear to potentially embrace a 5’ tag including a 5’ starting point with, e.g., a particular structure and/or functional characteristics, and such a structure was not disclosed in the original specification. Similarly, the original specification does not reference a “3’ transcription endpoint,” which also appears to potentially require a sequence having particular properties that are not disclosed in the originally filed specification. For this reason, while the intended meaning of language of the claims is not clear, it appears that the claims as presently written embrace material that was not originally disclosed. Accordingly, applicant's amendment of July 25, 2011 introduces additional new matter.

As a courtesy to applicant, it is noted that the specification does provide basis for a ditag that includes “paired 5’ and 3’ signature sequences (tags) of a transcript in a

ditag" that delineate "the starting and ending points of transcripts," as noted above. Further, paragraphs 87 and 100 disclose ditags of particular lengths, and reference ditags including, e.g., a tag of 8-16 base pairs, or 16-20 base pairs, from each of the 5' and 3' termini. Thus, applicant may wish to consider, e.g., clearly defining the tags of the ditag by reference to a fragment of specific length from each of the 5' and 3' ends of a full-length cDNA (which would find basis in the specification and also clearly delineate that which is claimed).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANA JOHANNSEN whose telephone number is

(571)272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634